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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,658	09/14/2000	Andrew D. Ellington	119927-1021	9207

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EXAMINER

GIBBS, TERRA C

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/661,658

Applicant(s)

ELLINGTON ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7, 12-19, 21, and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12-19 and 26-28 is/are rejected.
- 7) ☒ Claim(s) 7 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date September 30, 2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This Office Action is a response to Applicants Amendment and Remarks filed December 30, 2003.

Claims 6, 8-11, 20, and 22-25 have been canceled. Claims 1-5, 7, 12-19, 21, and 26-28 are pending in the instant application. Claims 1-5, 7, 12-19, 21, and 26-28 have all been amended.

Claims 1-5, 7, 12-19, 21, and 26-28 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Information Disclosure Statement***

The information disclosure statement filed September 30, 2003 is acknowledged. However, reference C57 has not been considered because it is not a proper reference. The cited references issued in the PCT International Search Report for PCT/US 02/25319, mailed June 17, 2003, have been listed in the information disclosure statement filed September 30, 2003, and have been considered by the Examiner. However, the PCT International Search Report itself cannot be considered because it is not a proper reference.

***Specification***

The disclosure is objected to because of the following informalities: The amendment to the specification filed December 30, 2003 is objected to because the last paragraph recites "Fig. 3a" where only "Figure 3" can be found. Appropriate correction is required.

***Oath/Declaration***

In the previous Office Action mailed July 30, 2003, the oath or declaration was indicated as being defective. **This is withdrawn** in view of Applicants Remarks filed December 30, 2003. Specifically, the Examiner agrees that the original Declaration did acknowledge the filing of the provisional application for which the instant application claims benefit.

***Nucleotide and/or Amino Acid Sequence Disclosure***

In the previous Office Action mailed July 30, 2003, it was noted that the application was not in compliance with the sequence rules set forth in 37 C.F.R. §1.821-1.825. **This is withdrawn** in view of Applicants Amendment filed December 30, 2003. Specifically, Applicants amendment to Figures 2A, 2B, and 3 to include sequence identifies obviates this non-compliant objection.

***Claim Rejections - 35 USC § 112***

In the previous Office Action mailed July 30, 2003, claims 1-5, 7, 12-19, 21, and 26-28 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This rejection is withdrawn** in view of Applicants Amendment to the claims filed December 30, 2003. Specifically, Applicants amendment to the claims to recite, "Group I intron oligonucleotide" and "aptamer oligonucleotide" obviates the instant rejection, since these terms would be recognized by one of skill in the art. Additionally, the Examiner agrees that the term "aptazyme" is an art-recognized term.

In the previous Office Action mailed July 30, 2003, claims 1-5, 7, 12-19, 21, and 26-28 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is withdrawn** in view of Applicants Amendment to the claims filed December 30, 2003. Specifically, Applicants amendment to the claims to recite, "Group I intron oligonucleotide" and "aptamer oligonucleotide" obviates the instant rejection, since these terms would be recognized by one of skill in the art. Additionally, the Examiner agrees that the term "aptazyme" is an art-recognized term.

After careful reconsideration of the claims, the following rejections have been made of record. It is noted that the following are new rejection(s):

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 12-19, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soukup et al. (Proc. Natl. Acad. Sci, 1999 Vol. 96:3584-3589, Applicant's reference [C51], filed September 30, 2003) or Robertson et al. (Nucleic Acids Research, 2000 Vol. 28:1751-1759, Applicant's reference [C44], filed September 30, 2003).

Claim 1-5, 12-19, and 26-28 are drawn to an allosteric ribozyme comprising a Group I intron oligonucleotide and an aptamer oligonucleotide, wherein the kinetic parameters of the Group I intron vary in response to the interaction of an allosteric effector molecule.

Soukup et al. teach an allosteric ribozyme comprising a double-stranded hammerhead ribozyme and an anti-flavin (FMN) aptamer (see Figures 1A and 5A, I(f)), an anti-theophylline aptamer, or an anti-ATP aptamer (see Figure 5A, I(t) and I(a), respectively), wherein the kinetic parameters of the hammerhead ribozyme vary in response to the interaction of an allosteric effector molecule.

Robertson et al. teach an allosteric ribozyme comprising a double-stranded small ribozyme ligase and an anti-theophylline aptamer, (see Figure 5a-d), wherein the kinetic

parameters of the ligase ribozyme vary in response to the interaction of an allosteric effector molecule.

It is further noted that the hammerhead ribozyme and the ligase ribozyme comprising an anti-theophylline aptamer disclosed by Soukup et al. and Robertson et al., respectively is attached at the same point as the instant Group I intron comprising an anti-theophylline aptamer of Applicants invention, as evidenced by Thompson et al. (BMC Biotechnology, 2002 Vol. 2:1-12, see page 2, first column).

Soukup et al. and Robertson et al. do not teach a Group I intron.

One of ordinary skill in the art would readily accept that ribozymes, in general, are RNA that can act as enzymes by catalyzing the cleavage or ligation of other target RNA molecules. Generally, engineered ribozymes bind target RNA in a sequence specific manner to cleave or ligate their targets in a *trans*-acting manner. Since all ribozymes function similarly, they are considered to be art-recognized functional equivalents. Thus, it is the Examiner's position that one of ordinary skill in the art would recognize that the hammerhead ribozyme (as taught by Soukup et al.), the ligase ribozyme (as taught by Robertson et al.), or the Group I intron ribozyme are functionally equivalent.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing to substitute the hammerhead ribozyme and anti-theophylline aptamer as taught by Soukup et al. or the ligase ribozyme and anti-theophylline aptamer as taught by Robertson et al. with the Group I intron and aptamer of Applicant's invention, since a Group I intron would have been considered to be functionally equivalent to the prior art

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hammerhead or ligase ribozymes. One of ordinary skill in the art would have been motivated to make an allosteric ribozyme comprising a Group I intron oligonucleotide and an aptamer oligonucleotide, wherein the kinetic parameters of the Group I intron vary in response to the interaction of an allosteric effector molecule since Soukup et al. and Robertson et al. generally teach ribozyme engineering strategies can be used to develop new RNA molecular switches that function in response to the presence of almost any effector molecule for developing regulatable gene therapeutics (see Soukup et al., Abstract).

Therefore, the instant invention would have been prima facie obvious to one of ordinary skill in the art at the time of filing.

### ***Claim Objections***

Claims 7 and 21 are objected to because they depend on a rejected-based claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LeGuyader John can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg  
March 1, 2005



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